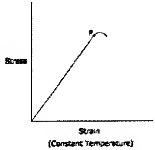
REMARKS

Favorable reconsideration is respectfully requested in light of the above amendments and the following comments. Previously withdrawn claims 1-22 have been canceled. New claims 28-36 have been amended to round out the potential scope of protection. No new matter has been added as a result of these amendments.

Prior to addressing the prior art rejections, Applicants wish to generally discuss the invention. The claimed invention is directed to a medical device that includes a linear elastic member. In some cases, the linear elastic member may be a linear elastic nickel-titanium alloy, although the independent claims do not expressly recite a nickel-titanium alloy. A portion of the linear elastic member may be heat treated to provide a portion of the linear elastic member with superelasticity.

By reviewing the comments provided by the Examiner in the most recent Office Action and the Advisory Action, it is apparent that the Examiner has either failed to understand or failed to appreciate the distinct differences between a linear elastic material and a superelastic material. To assist the Examiner, Applicants provide herewith a detailed discussion outlining the distinct differences between linear elasticity and super elasticity.

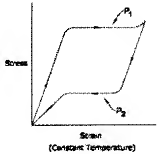
As one of skill in the art will recognize, the terms linear elasticity and superelasticity describe two very different types of elasticity. Linear elasticity means that a material has a stress-strain curve that is substantially linear. An example idealized stress-strain curve of a linear elastic material is reproduced below:



As shown in this graph, the portion of the curve between the origin and the point P, sometimes called the proportional region of the curve, can be substantially linear. Past the point P (sometimes called the proportional limit of the material), the material becomes deformed, and will not fully recover its original shape. If the stress is removed

from the material before the material reaches the point P, the material can return to, or near to, the origin, in some cases substantially along the same line.

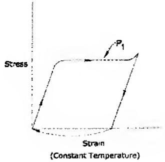
In contrast, materials that are characterized as superelastic generally have a very different stress-strain curve and have two crystal phase structures. The two phases are called austenite and martensite. An idealized curve of a superelastic material is reproduced below, where the arrows show the direction of the path taken by the material through a stress-strain cycle.



Such a superelastic stress-strain curve is very different from a linear elastic curve. As the material is placed under strain, the curve initially has a relatively steep slope. At a certain point, however, the slope flattens out. This area of the curve is marked as P_1 in the above graph, and is often called the "superelastic flag," or "superelastic plateau," portion of the curve. Generally, under certain conditions, stressing superelastic materials can cause the material to change from its austenite to its martensite crystal structure. Such production of the martensite phase is often called stress-induced martensite. Further, under certain conditions, when the stress is removed from the material, the material will seek out, and return to, its original austenite phase. As it returns to the austenite phase from its stress-induced martensite phase, it can go through another superelastic plateau, as shown in the graph at P_2.

Without being bound by the theory, the driving force behind superelasticity (and the presence of the superelastic plateaus in the stress-strain curve) is thought to be the change in the crystal structure of the material between austenite and martensite. In contrast, linear elastic materials normally do not have a phase change in the elastic, or proportional, region of the curve. Thus, there is a distinct structural difference between a linear elastic material and a superelastic material.

As a further note, the superelastic materials described above can also exhibit shape memory properties under certain conditions. Shape memory is the ability of a material to be deformed and later assume its original shape. With the above described superelastic materials, certain temperature changes can typically cause the material to return to its original shape. Shape memory materials are typically originally in an austenite state. The material can be stressed, causing the formation of stress-induced martensite. However, the material may be at a temperature at which, when the stress is removed, the material does not revert to its austenite phase. As such, there is no driving force to cause the material to be elastic in such a case. Rather, the material will remain deformed until the material is exposed to a temperature that causes the material to revert to the austenite crystal phase. This return to the austenite phase can return the material to its original shape; in this way, the shape memory material "remembers" its original shape. An idealized stress-strain curve that describes this behavior is shown below:



The curve shows that two-phase shape memory materials can have a superelastic plateau on the extension portion of the curve (again, this plateau is marked P_1). However, when the stress is released, the material does not immediately recover all of the strain. All or a portion of the strain can be recovered by changing the temperature of the material, causing the material to return to its austenite phase and returning the strain (and in the process the original shape) along the dotted line shown on the curve.

The current application also highlights some of the above differences in properties, along with at least one additional difference. Figure 4 of the current application compares the stress-strain curves of a linear elastic and superelastic material. Again, the different shapes of the curves are shown in this figure. Also, the two graphs show a difference in the ultimate strength of a comparable linear elastic and superelastic

material (with the ultimate strength of a linear elastic material being the greater of the two).

As can be observed from the above graphs (and Figure 4 of the current application), materials that exhibit linear elasticity have significantly different properties when compared to materials with superelasticity or shape memory, and thus one of skill in the art will recognize and appreciate that linear elastic and superelastic/shape memory materials are mutually exclusive classes of materials. The different shape of the superelastic/ shape memory curves (again, thought to be caused by the change in the crystal structure of these materials) can allow elongate medical devices to more efficiently navigate tight turns in a patient's anatomy.

Specifically, the superelastic plateau region of the curve can allow these materials to be bent relatively easily within a certain region (the plateau region) of their stress-strain curves. On the other hand, if it is desired to provide for greater strength and force transfer along all or a portion of a device, a linear elastic material can be more appropriate. Although the linear elastic material may in some cases have less flexibility, it can have greater ultimate strength and can provide for transmission of greater forces. As such, these materials have significantly different properties, and a linear elastic material cannot be considered the equivalent of a superelastic or shape memory material.

Further, as noted in the current application (see paragraph [0024]), some linear elastic materials (e.g., some linear elastic Nitinol alloys) can be treated in order to make the material have austenite and martensite crystal structures, giving the material superelastic and/or shape memory properties. In the same way that hardened steel would not be the same as unhardened steel, these linear elastic and superelastic materials are simply not the same thing even though they may have the same stoichiometric ratio of components.

Moreover, Sahatjian et al. (U.S. Patent No. 5,238,004) clearly describe teach that linear elastic materials are different from super elastic materials. Indeed, this reference discloses using a linear elastic material as a starting point for forming a superelastic material. Very specific processing is required to make this transformation. One of skill in the art would recognize, from this reference, that a linear elastic material is structurally

and patentably different from a superelastic material, regardless of any incidental similarities in portions of their respective stress-strain graphs.

Further, Rooney et al. (U.S. Patent No. 6,306,105) recognize and describe distinct material differences between linear elastic materials and superelastic materials. See, for example, column 3, lines 19-39 of Rooney et al. It should be noted that both Sahatjian et al. and Rooney et al. are made of record in the Information Disclosure Statement filed concurrently herewith.

It should be abundantly clear, therefore, that a linear elastic material is different from a superelastic material. It should be clear, then, that none of the references actually disclose a medical device that includes a linear elastic member that has a super elastic region formed therein via application of an appropriate temperature.

Turning now to the art rejections, claims 23, 24, 26 and 27 stand rejected under 35 U.S.C. §102(e) as being anticipated by Eder et al., U.S. Patent No. 6,585,753. Claims 23, 24, 26 and 27 stand rejected under 35 U.S.C. §102(b) as being anticipated by Sagae et al., U.S. Reissue Patent No. 36,628, or McNamara et al., U.S. Patent No. 6,254,550. Claims 23, 24, 26 and 27 stand rejected under 35 U.S.C. §102(e) as being anticipated by Davis et al., U.S. Patent Publication No., 2004/0111044. Claims 23 and 24 stand rejected under 35 U.S.C. §102(b) as being anticipated by Sachdeva et al., U.S. Patent No. 5,683,245. Claims 23, 24, 25 and 26 stand rejected under 35 U.S.C. §102(b) as being anticipated by Kleshinski, U.S. Patent No. 5,776,162. Claims 23-26 stand rejected under 35 U.S.C. §102(b) as being anticipated by DiCarlo et al., U.S. Patent No. 6,540,849. Claims 23 and 27 stand rejected under 35 U.S.C. §102(b) as being anticipated by Kaisha, EP 0395098. Claim 27 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Sachdeva et al., U.S. Patent No. 5,683,245, Kleshinski, U.S. Patent No. 5,776,162, or DiCarlo et al., U.S. Patent No. 6,540,849. Claims 24 and 26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Kaisha, EP 0395098. Applicants respectfully traverse these rejections.

After carefully reviewing each of the cited references, Applicants respectfully maintain that none of the cited references appear to teach the claimed invention, individually or in combination. In the Advisory Action, the Examiner has asserted that "Applicant has presented no evidence that claimed subject material possesses any

property (e.g. linear elastic behavior) not present in any of the prior art materials." While "linear elastic" may define, at least in part, the stress-strain behavior of a linear elastic material, one of skill in the art will recognize that Applicants are claiming a material, not simply a particular property. Moreover, one of skill in the art would likely not interpret any of the cited references as expressly disclosing linear elastic material.

None of the cited references expressly disclose a linear elastic member that includes a portion thereof that is heat treated to expressly give the linear elastic member a superelastic portion thereof. Thus, the claimed invention is both novel and inventive over the myriad of cited references. Favorable reconsideration is respectfully requested.

Reexamination and reconsideration are respectfully requested. It is submitted that all pending claims are currently in condition for allowance. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at 612.677.9050.

Respectfully submitted,

DENNIS A. BOISMIER ET AL.

By their Attorney,

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Glenn M. Seager, Reg. No. 36,926
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, Minnesota 55403-2420
Tel: (612) 677-9050